

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF ALABAMA  
SOUTHERN DIVISION**

RENU MEDICAL, INC., )  
                          )  
Plaintiff,            )  
                          )  
vs.                    )    **CV 05-B-0949-S**  
                          )  
HYGIA HEALTH SERVICES, INC.; )  
TRACY WOOD COMAS; SCOTT )  
COMAS,                )  
                          )  
Defendant.            )

**MEMORANDUM OPINION**

This case is presently pending before the court on defendants' Motions for Summary Judgment, (docs. 19 and 23),<sup>1</sup> and plaintiff's Motion for Leave to File Out of Time, (doc. 25). Plaintiff ReNu Medical, Inc., has sued defendants Hygia Health Services, Inc., Tracy Wood Comas, and Scott Comas, alleging breach of contract and fraud. Upon consideration of the record, the submissions of the parties, the arguments of counsel, and the relevant law, the court is of the opinion that Hygia's Motion for Summary Judgment, (doc. 19), is due to be granted in part and denied in part; the Comases' Motion for Summary Judgment, (doc. 23), are due to be granted; and ReNu's Motion for Leave to File Out of Time, (doc. 25), is due to be denied.

---

<sup>1</sup>Reference to a document number, ["Doc. \_\_\_\_"], refers to the number assigned to each document as it is filed in the court's record.

## **I. SUMMARY JUDGMENT STANDARD**

Pursuant to Fed. R. Civ. P. 56(c), summary judgment is appropriate when the record shows “that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears the initial burden of showing no genuine issue of material fact and that it is entitled to judgment as a matter of law. *See Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir. 1991); *see also Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970). Once the moving party has met its burden, Rule 56(e) requires the non-moving party to go beyond the pleadings and show that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). A dispute is genuine “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

In deciding a motion for summary judgment, the court’s function is not to “weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.” *Id.* at 249. Credibility determinations, the weighing of evidence, and the drawing of inferences from the facts are left to the jury, and, therefore, evidence favoring the non-moving party is to be believed and all justifiable inferences are to be drawn in its favor. *See id.* at 255. Nevertheless, the non-moving party need not be given the benefit of every inference but only of every *reasonable* inference. *See Brown v. City of Clewiston*, 848 F.2d 1534, 1540 n.12 (11th Cir. 1988).

## **II. STATEMENT OF FACTS**

Defendants Scott Comas and Tracy Wood Comas founded defendant Hygia Health Services, Inc., in April 1999. (Doc. 19, Ex. 1 at 1.) The purpose of Hygia “was and is to reprocess semi-critical and non-critical medical devices for hospitals.” (*Id.*) “Reprocessing is done by high-level disinfection.” (*Id.*) Historically, such medical devices were used one time and discarded. (*Id.*)

The Federal Drug Administration [“FDA”] is responsible for overseeing reprocessing of medical devices; however, it had no formal program for approving specific reprocessed medical devices before 2000. (*Id.*) In 2000, the FDA announced that it would require companies to have authorization in the form of 510(k)s and Substantial Equivalency Letters to reprocess medical devices. (*Id.*) A “510(k)” is “a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA).” US Food and Drug Administration, Premarket Notification [510(k)] at <<<http://www.fda.gov/cdrh/devadvice/314.html>>>. “Until the applicant receives an order [from the FDA] declaring a device substantially equivalent, the applicant may not proceed to market the device.” 21 C.F. R. § 807.100(a)(5).

“Hygia developed protocols for reprocessing medical devices, a software program for tracking reprocessed devices, and a record-keeping system designed specifically for this

business.” (Doc. 19, Ex. 1 at 2.) It applied for a number of 510(k)s as required by the FDA. (*Id.* at 1-2.)

On December 29, 2000, Hygia entered into a Business Core and Software Licensing Agreement with ReNu, formerly known as Hygia Health Services West, Inc., which had been formed by Bruce Pierson and Randall K. Long. (*Id.*, Ex. 2; *id.*, Ex. 9 at 27-28.) The Business Core and Software Licensing Agreement defined the “Business Core” as “Certain documentation, procedures and protocols used and followed by Hygia in the operation of its non-critical medical products reprocessing business, which Business Core is more specifically described on Exhibit A, attached hereto and incorporated herein by this reference.” (*Id.*, Ex. 2 § 1.1.) Exhibit A to the Licensing Agreement lists “Shared 510(k)s filings for current and new products.” (*Id.*, Ex. 2, attach. at 0022.) The “Business Package” is the “Business Core, together with the Core Software.” (*Id.*, Ex. 2 § 1.2.) The Licensing Agreement stated:

HYGIA hereby grants to WEST a non-transferable license for use of the Business Core and the Core Software . . . . Said License shall allow WEST the ability to use the Business Core and the Core Software in any or all locations in which WEST maintains a business presence. Said license shall be exclusive (*except with regard to HYGIA*) with regard to the states of Washington, Oregon, California, and Colorado, and non-exclusive elsewhere. *The exclusive license granted in the four mentioned states is not intended to limit HYGIA's use of the Business Package, or any part thereof, in said states. . . . Rather, it is intended to prohibit HYGIA from licensing the Business Package, or any part thereof, to a third party in the four mentioned states.*

(*Id.* § 2.1.1 [emphasis added].) The Licensing Agreement provided that “[t]itle, full ownership and all proprietary rights to the Business Package . . . remain[ed] with HYGIA.”

(*Id.* § 2.2.1.) ReNu paid Hygia \$250,000 plus 3% gross revenues under the Licensing Agreement. (*Id.* §§ 6.1.1, 6.1.2.) Alabama law governs the Licensing Agreement. (*Id.* § 10.6.)

On May 21, 2002, Geoff Fatzinger, an employee of Hygia, sent ReNu the following letter:

Let it be known to all concerned that Hygia Health Services, Inc. in Birmingham[,] Alabama does hereby willingly ***assign and authorize for use*** the below listed premarket submissions to Hygia West, Inc. registration number 303450 in Everett[,] Washington. This ***assignment and authorization*** to use is “As Is” with ***no authority to alter, amend or otherwise change the scope, intent, content or material fact located therein***. I further certify that as the Director of Compliance and regulatory Affairs, I have been given, by the CEO and Board of Directors, the appropriate responsibility and ultimate authority for all actions pertaining to such activities.

(*Id.*, Ex. 5 [emphasis added].)<sup>2</sup>

The business relationship between Hygia and ReNu deteriorated and the parties mediated the termination of their business relationship. After mediation, on June 9, 2003, the parties signed a Settlement Agreement. (*Id.*, Ex. 3.) The Settlement Agreement provided that ReNu’s predecessor would “***maintain access to all currently assigned*** 510(k)s and current pending 510(k)s.” (*Id.* [emphasis added].)

---

<sup>2</sup>Hygia claims that Fatzinger did not have authority to sign the assignment. (Doc. 19 at 4.) However, it “stipulates as to the genuineness” of the document for purposes of summary judgment only. (*Id.* at 4-5.)

Thereafter, the parties entered into a Mutual Release and Settlement Agreement arising out of the mediation. (*Id.*, Ex. 4) The Mutual Release and Settlement Agreement stated:

Hygia has *previously assigned* to West the following 510 Ks: K012650 Nu-Tech Foot Wrap; K102657 Nu-Tech Calf Wrap; K012956 Nu-Tech Combo; K012417 Kendall SCD; K012651 Huntleigh Foot; K01254 Huntleigh Flowtron; and K012715 Nellcor Probes. To the extent permissible by law, *such assignments are hereby ratified and confirmed*. The Parties recognize and agree, however, that there is a legal question as to the assignability of K012715, which is presently pending. Thus, the parties agree that Hygia will furnish to West full and complete information to keep West informed of the status of the submission of said 510K, and in the event of approval of said 510K by the FDA, Hygia will assign the same to West within ten days thereafter, and will simultaneously therewith furnish West with a complete copy of the submittal and 510K.

(*Id.* [emphasis added].)

Pierson and Long testified that the 510(k)s listed above were “assigned” to ReNu in the “initial licensing agreement,” the settlement agreements, and the Fatzinger letter. (*Id.*, Ex. 9 at 33, 42, 44-46; *id.*, Ex. 10, at 18-21.) Long testified that the Fatzsinger letter had the same intention as the Licensing Agreement. (*Id.* at 20-21.)

Prior to the termination of their business relationship, Hygia and ReNu competed for business and sometimes worked together jointly. (See *id.*, Ex. 6 at 1.) After the termination of their business relationship, Hygia and ReNu continued to compete for business related to the reprocessed medical devices; however, ReNu did not continue to pay Hygia 3% of its gross sales as it had under the licensing agreement. (*Id.*, Ex. 1 at 2; *id.*, Ex. 4 ¶ 2; *id.*, ex. 9 at 49-50.) After the termination of the business relationship, ReNu applied for 510(k)s in its

own name for the reprocessed medical devices at issue in this case, except the Nellcor Probe.

(*Id.*, Ex. 9 at 79-82, 150-52; *id.*, Ex. 10 at 38.)

ReNu contends that Hygia transferred ownership of the 510(k)s at issue in this case. Although the parties competed for business both before and after the settlement agreements were signed, ReNu did not complain about Hygia's use of the 510(k)s until it filed the instant action in May 2005. (*Id.*, Ex. 10 at 37.)

According to plaintiff's Amended Complaint, the Comases, individually and as agents of Hygia,

represented to Plaintiff that all 510ks which were the subject of the controversy between plaintiff and Defendant Hygia would be assigned to Plaintiff. Said representations were false, and were known by [Scott and Tracy Wood Comas] to be false. . . . Said representations were made for the purpose of inducing the Plaintiff to sign the written Settlement Agreement between Plaintiff and Defendant Hygia.

(Doc. 13 ¶ 31; *see also id.* ¶¶ 25, 29, 33.) During his deposition, Long testified:

Q. What did Tracy tell you that was a lie that brings this fraud count to us?

A. I don't know anything that Tracy told me –

...

A. – that she verbally told me that is direct fraud. It's the actions of Hygia and what they haven't given us, what they have continued to do as far as claiming that they are theirs when indeed they are ours. And I guess to take it one step further, if they are not ours, then what did we pay all the money for and what did we go through the mediation settlement for and decline to push our request for monetary damages in lieu of the full-blown assignment from the 510(k)s to us? That's the fraud.

Q. Let me see here. The fraud you're telling me about, then, is failure to give you everything that you were entitled to under the initial licensing agreement, one thing?

A. No.

Q. That's not it?

A. That and the mutual agreement.

Q. Then you do agree with me that that's one thing?

A. That's one thing that started.

Q. I'm just trying to see what the claim is today.

A. I'm here for you.

Q. Secondly, there was some letter that says we are assigning to you – there's a release that was signed, said we are assigning, we affirm the previous assignment, whatever. But those documents that you've told us about today that you say gives rise to the ownership in ReNu, the fraud is that Tracy says today, as far as you know, that that didn't give you title, therefore that's the fraud; is that it?

A. In my opinion, yes.

Q. Okay. But you've had no conversation with her other than the written document about that issue?

A. Correct.

Q. Same answer for Scott?

A. Correct.

Q. Same answer for anybody at Hygia Health Services?

A. Correct.

Q. Do you know as we sit here today what was in the mind of each of these individuals when they wrote you those letters?

A. Do I know exactly what was in their minds? Of course not.

Q. No, not exactly. Just generally.

A. Of course not. I know what the document's saying. They are very clear. I understand English and grammar, and each word has a meaning, and it's very clear.

Q. Okay.

(Doc. 19, Ex. 9 at 128-30.)

### **III. DISCUSSION**

#### **A. BREACH OF CONTRACT – HYGIA**

In its Second Amended Complaint, ReNu alleges that Hygia breached their assignment agreement by continuing to market the reprocessed devices covered by the 510(k)s. (Doc. 13 ¶¶ 14, 17.) Hygia, apparently conceding the ambiguity of the documents that allegedly created the assignment, argues that the relationship and conduct of the parties show that the intent of the parties was to convey only “the right[s] to use, [to] have access to, and [to] share” the 510(k)s and that ReNu’s conduct “reflects a mind set and recognition that [it] did not own the 510(k)s at issue.” (Doc. 19 at 9, 16-18.)

Before discussing the merits of Hygia’s argument, the court notes that ReNu has filed a Motion for Leave to File Out of Time. (Doc. 25.) Hygia filed its Motion for Summary Judgment on May 30, 2006, (doc. 19); therefore, ReNu’s Opposition was due on June 20,

2006.<sup>3</sup> ReNu filed its Motion for Leave to File Out of Time, with its Opposition to Hygia's Motion attached, on September 25, 2006, (doc. 25), which was more than three months past its deadline.

The Exhibit A to the court's Scheduling Order states:

This exhibit contains specific, mandatory instructions regarding the preparation and submission of briefs and evidentiary materials in support of and in opposition to potentially dispositive motions. **These instructions must be followed explicitly. Except for good cause shown, briefs and evidentiary materials that do not conform to the following requirements may be stricken.**

(Doc. 12, Ex. A at 1 [emphasis in original].) As cause for its late filing, ReNu's Motion states, "Through clerical error on the part of Plaintiff's counsel, the deadline for filing the Plaintiff's Response to Defendant's Motion for Summary Judgment . . . was incorrectly calendared, and thus not timely filed." (Doc. 25 ¶ 1.)

To establish good cause, ReNu must show that it could not meet the deadline for filing its Opposition despite its diligence as to the matter. *Sosa v. Airprint Systems, Inc.*, 133 F.3d 1417, 1418 (11th Cir. 1998)(citing Fed. R. Civ. P. 16 advisory committee's note and *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 609 (9th Cir. 1992)). The court finds that ReNu has not demonstrated that it acted diligently. Therefore, its Motion for Leave to File

---

<sup>3</sup>According to Exhibit A to the court's Scheduling Order, the non-moving party's opposition to a Motion for Summary Judgment is due 21 days after the Motion is filed. (Doc. 12, Ex. A at 1 ["The responsive submission of the party opposing the motion for summary judgment shall be filed not later than 21 days after the motion for summary judgment is filed."].)

Out of Time, (doc. 25), is due to be denied.

Nevertheless, Hygia's Motion for Summary Judgment will not be granted unless, based on the evidence it has submitted, the record contains no disputed issues of material fact and it is entitled to judgment as a matter of law. *Coats & Clark*, 929 F.2d at 608.

Pursuant to Alabama law,

Whether a contract is ambiguous is a question of law for the trial court to determine. In interpreting a contract, the words of the agreement will be given their ordinary meaning. An instrument is unambiguous if only one reasonable meaning clearly emerges. If the terms within a contract are plain and unambiguous, the construction of the contract and its legal effect become questions of law for the court and, when appropriate, may be decided by a summary judgment. ***However, if the terms within the contract are ambiguous in any respect, the determination of the true meaning of the contract is a question of fact to be resolved by a jury.***

*Reeves Cedarhurst Development Corp. v. First Amfed Corp.*, 607 So.2d 184, 186 (Ala. 1992)(emphasis added; internal citations and quotations omitted). “If one must go beyond the four corners of the agreement in construing an ambiguous agreement, the surrounding circumstances, including the practical construction put on the language of the agreement by the parties to the agreement, are controlling in resolving the ambiguity.” *Alfa Life Ins. Corp. v. Johnson*, 822 So.2d 400, 405 (Ala. 2001).

ReNu contends that Hygia agreed to “assign” certain of its 510(k)s to it. Generally, “[a]n assignment is the transfer by one of his right or interest in property to another.” *Williams v. Williams*, 158 So. 2d 901, 903 (Ala. 1963). However, “[a] license does not pass any interest in the property to the licensee. It only makes an action lawful, which without a

license would have been unlawful.” *Shearer v. Hodnette*, 674 So.2d 548, 551 (Ala. Civ. App. 1995). “Whether a transfer constitutes a sale [or an assignment of rights] or license is determined by the substance of the transaction and a transfer will suffice as a sale [or assignment of rights] if it appears from the agreement and surrounding circumstances that the parties intended that the [transferor would] surrender all his substantial rights.” *Hooker Chemicals and Plastics Corp. v. United States*, 591 F.2d 652, 658 (Ct. Cl. 1979); *see also Pope Manufacturing Co. v. Gormully & Jeffery Manufacturing Co.*, 144 U.S. 248, 250 (1892)(assignment vests legal title in assignee; license enables licensee to make, use, or sell but does not give him legal title).

The court finds that the agreements between Hygia and ReNu are ambiguous and that the intent of the parties presents a question of fact for the jury.<sup>4</sup> Neither the Settlement

---

<sup>4</sup>Hygia contends that this court can resolve the ambiguity as a matter of law by looking to the parties’ conduct. (See doc. 19 at 9-10.) In support of its argument that “[e]ven where there is an ambiguity, summary judgment is not precluded,” Hygia cites *Vesta Fire Insurance Corp. v. Liberty National Life Insurance Co.*, 893 So. 2d 395. (Doc. 19 at 9.) The court notes, however, that the *Vesta Fire* case limits summary judgment on ambiguous contracts to situations where the ambiguity can be resolved by reference to “established rules of contract construction.” *Vesta Fire*, 893 So. 2d at 404 (quoting *Voyager Life Insurance Co. v. Whitson*, 703 So. 2d 944, 948 (Ala. 1997)(emphasis omitted)). The *Vesta Fire* case held, “In short, a court is to evaluate the contract on its face and apply rules of contract construction in an effort to resolve ambiguities before submitting the case to a jury.” *Id.* (citing *Air Conditioning Eng’rs v. Small*, 65 So. 2d 698, 703 (Ala. 1953); *Lutz v. Van Heynigen Brokerage Co.*, 75 So. 284, 288 (Ala. 1917); *Boykin v. Bank of Mobile*, 72 Ala. 262, 269 (1882)).

Because Hygia contends that it is entitled to judgment as to ReNu’s breach-of-contract claims based, in part, on the parties’ course of conduct, the question of the intent of the parties as to their concededly ambiguous agreement is for a jury, not the court.

Agreement nor the Mutual Release and Settlement Agreement actually transfer the ownership of or license the use of the 510(k)s. These documents refer only to previously assigned 510(k)s. Therefore the court finds these agreements did not transfer ownership of the 510(k)s to ReNu. The License Agreement was voided by the Settlement Agreements, and, by its terms, it did not transfer ownership of the 510(k)s to ReNu. The remaining document at issue is the Fatzsinger letter, which purports to assign certain 510(k)s to ReNu. However, simultaneously, the Fatzsinger letter states that Hygia “assign[s] **and** authorize[s] for use” the 510(k)s to ReNu, but Hygia limited ReNu’s authority to change the 510(k)s at issue. (Doc. 19, Ex. 5.) If Hygia intended to “assign” or transfer the ownership of the 510(k)s to ReNu, it could not have authorized or limited the use of the 510(k)s, which if assigned would no longer be the property of Hygia.

In short, the limitations in the Fatzsinger letter on ReNu’s use of the 510(k)s creates an ambiguity as to whether Hygia intended to transfer ownership of the 510(k)s or merely to give ReNu permission to use the 510(k)s. This ambiguity presents an issue of fact for the jury.

Therefore, Hygia’s Motion for Summary Judgment, (doc. 19), is due to be denied as to ReNu’s breach of contract claim.

## **B. FRAUD – HYGIA, SCOTT COMAS, AND TRACY WOOD COMAS**

ReNu alleges that the Comases, individually and as agents of Hygia, misrepresented that they would assign or transfer the ownership of the 510(k)s at issue for purposes of

inducing ReNu to sign the Settlement Agreements. (Doc. 13 ¶¶ 25, 29, 31,33.)

The Comases filed their Motion for Summary Judgment on August 7, 2006, (doc. 23); ReNu filed its Opposition to the Comases' Motion for Summary Judgment on September 26, 2006, (doc. 26). ReNu's Opposition was untimely filed,<sup>5</sup> and it did not seek leave of the court to file its Opposition after the deadline. Therefore, the court will *sua sponte* strike plaintiff's Response to the Comases' Motion for Summary Judgment, and it has not considered the Response in deciding the Comases's Motion for Summary Judgment.

The Settlement Agreement states that all existing agreements, which included the Licensing Agreement, between the parties are void, and that ReNu will "maintain[ ] access to all currently assigned 510Ks and to any currently pending 510Ks." (Doc. 19, Ex. 3 at 1.) Also, the Mutual Release and Settlement Agreement states that the "licensing agreement" is terminated, and this document also states that the "previously assigned" 510(k)s are "ratified and confirmed." (*Id.*, Ex. 4 ¶¶ 2, 6.) Nothing in either Settlement Agreement states that Hygia was assigning or transferring ownership of any 510(k)s to ReNu in the Settlement Agreements. Indeed, both documents refer specifically to past assignments.<sup>6</sup> (*See id.* ¶ 6.)

In its Second Amended Complaint, ReNu contends that the Comases, individually and as agents of Hygia, misrepresented that Hygia would assign the 510(k)s at issue to ReNu

---

<sup>5</sup>See, *supra*, note 3.

<sup>6</sup>There is a reference to the assignment of the 510(k) for the Nellcor probe in the Mutual Release and Settlement Agreement; it refers to some "legal question" about this assignment, which has not been discussed by the parties.

during settlement negotiations. Because its claim is “one based upon a promise to act or not to act in the future,” plaintiff’s claim is a claim of promissory fraud. *Ex parte Michelin North America, Inc.*, 795 So. 2d 674, 678 (Ala. 2001)(quoting *Padgett v. Hughes*, 535 So. 2d 140, 142 (Ala. 1988)).

The elements of fraud are (1) a false representation (2) of a material existing fact (3) reasonably relied upon by the plaintiff (4) who suffered damage as a proximate consequence of the misrepresentation. To prevail on a promissory fraud claim . . . , two additional elements must be satisfied: (5) proof that at the time of the misrepresentation, the defendant had the intention not to perform the act promised, and (6) proof that the defendant had an intent to deceive.

*Id.* at 678-79 (citations omitted).

The court finds that the record is devoid of any evidence that ReNu reasonably relied on the Comases’ representations during the settlement negotiations. Alabama law provides, “[F]raud or misrepresentation cannot be predicated upon a verbal statement made *before* execution of a written contract when a provision in that contract contradicts the verbal statement.” *Tyler v. Equitable Life Assurance Society*, 512 So. 2d 55, 57 (Ala. 1987)(citing *Taylor v. Moorman Manufacturing Co.*, 475 So.2d 1187 (Ala. 1985))(emphasis added). Despite ReNu’s contentions as to the Comases’ statements during settlement negotiations, nowhere in the Settlement Agreement or the Mutual Release and Settlement Agreement does Hygia promise to assign the 510(k)s to ReNu. Therefore, under Alabama law, ReNu did not reasonably rely on any alleged misrepresentations made verbally during settlement negotiations and before execution of the Settlement Agreement and the Mutual Release and Settlement Agreement.

Defendants' Motion for Summary Judgment as to ReNu's fraud claims are due to granted and such claims are due to be dismissed.

**CONCLUSION**

For the foregoing reasons, the court is of the opinion that there are no material facts in dispute and defendants are entitled to judgment as a matter of law as to plaintiff's fraud claims. However, the court finds a question of fact exists such that Hygia is not entitled to summary judgment as to plaintiff's breach of contract claim. An Order denying plaintiff's Motion for Leave to File Out of Time, (doc. 25); granting in part and denying in part defendant Hygia's Motion for Summary Judgment, (doc. 19); and granting the Motion for Summary Judgment filed by defendants Scott Comas and Tracy Wood Comas, (doc. 23), will be entered contemporaneously with this Memorandum Opinion.

**DONE**, this 21st day of March, 2007.

*Sharon Lovelace Blackburn*  
SHARON LOVELACE BLACKBURN  
CHIEF UNITED STATES DISTRICT JUDGE